

Nov 21 2002 13:19

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P. 1

FILE No. 733 11/21 '02 13:05 ID:SFU-MOLECULAR BIOLOGY

PAGE 2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Kitson

Application No.: 09/780,060

Filed: 2/9/2001

Title: Skin Treatment Compositions and Methods of Use

Attorney Docket No.: TDIG.P-001

Group Art Unit: 1616

Examiner: M. Lamm

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GROUP 1600

DECLARATION IN SUPPORT OF
SUPPLEMENTAL RESPONSE AFTER FINAL

OFFICIAL

The undersigned inventor(s) hereby declare as follows:

1. We understand that the Examiner considering the above-referenced case has asserted that compositions 26 and 27 of the Kawada reference would inherently crystallize, and would therefore meet the limitations of our claimed invention. From the perspective of one skilled in the art, we disagree.
2. Compositions 26 and 27 of Kawada both contain cholesteryl sodium sulfate. Our research with this material shows that it does not crystallize to the same extent as cholesterol.
3. Compositions 26 and 27 of Kawada also contain oleylamino-octadecane 1,3 diol. This compound has a *cis*-double bond in the chain (oleyl is 9,10 unsaturated). Lipids with this stereochemistry are sterically unlikely to crystallize (See page 5, ¶ 2 of our application).

I hereby certify that this paper and any attachments named herein are transmitted to the United States Patent and Trademark Office, Fax number: 703-872-9307 on November 21, 2002.

Marina T. Larson
Marina T. Larson, PTO Reg. No. 32,038

November 21, 2002
Date of Signature

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p. 2

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PAGE 3

4. Compositions 26 and 27 are said to be hydrated with a very small amount of water (200 μ l/20 g) and subjected to freeze thaw cycles. In contrast, the present invention is directed to aqueous formulations, and the lipid level in the aqueous buffer in example 1 is 8 mg/ml. Persons skilled in the art know that water and the pH and salt concentration of that water are important determinants in the phase behavior of lipids. The exemplary material in the present application has 125,000 times more water than the hydrated lipids of the reference.

5. For all of these reasons, we do not think it would be reasonable to expect that the Kawada compositions would crystallize.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that those statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

dated:


Neil Kinton

dated: Nov 21 2002


Jennifer Thewalt